DEC 1 1 2001

K010443

# CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating

**Submitter Information:**

Name and Address:
Terumo Cardiovascular Systems Corp.
125 Blue Ball Road
Elkton, MD 21921

Contact Person:
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125 Blue Ball Road
Elkton, MD 21921
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: November 30, 2000

**Device Names:**

| Proprietary Name | Classification Name | Common Name |
|---|---|---|
| CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating | Cardiopulmonary Bypass Oxygenator | Oxygenator |
| | Cardiopulmonary Bypass Heat Exchanger | Heat Exchanger |
| | Cardiopulmonary Bypass Blood Reservoir | Blood Reservoir |
| | Cardiopulmonary Bypass Defoamer | Defoamer |
| | Cardiopulmonary Bypass Cardiotomy Suction Line Blood Filter | Blood Filter |
| | Cardiopulmonary Bypass Stopcock, Manifold, Fitting | Sampling Manifold with Stopcocks |

**Predicate Device:**
The device submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and specifications to the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir (K960074).

**Intended Use:**
The CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating is used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integral heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The (detachable) hardshell reservoir is used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line (via gravity or vacuum assisted venous drainage procedures). The reservoir contains a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal.

The X-Coating is a biocompatible coating that is applied to the blood contacting surfaces of the oxygenator and reservoir to reduce the adhesion of platelets to the surfaces of the device. The CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating can be used in procedures lasting up to 6 hours.

**Principles of Operation and Technology:**
The design of the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating is such that blood is collected into the reservoir via gravity or external vacuum. Blood may enter via the venous inlet port and/or the cardiotomy inlet port. The reservoir contains filtering devices to remove particulate matter and air. Blood is then pumped from the reservoir into the heat exchanger device whereby blood temperature is controlled. After the blood exits the heat exchanger, it enters the oxygenator device whereby gas transfer (introduction of oxygen and removal of carbon dioxide) occurs. After gas transfer has occurred, the blood exits the device and is pumped towards the patient.

**Design and Materials:**
The design of the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating provides a semi-integral device whereby the oxygenator and heat exchanger are joined together, while the hardshell reservoir can be detached from the device assembly.

The major materials that are used in the construction of the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating include

polycarbonate, stainless steel, polyvinylchloride, polyurethane, polyester, polypropylene, polyethylene and X-Coating.

**Performance Evaluations:**
The performance of the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating submitted in this premarket notification is substantially equivalent to the performance of the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir. The following evaluations were conducted to demonstrate equivalence in performance:

- Gas Transfer
- Effects on Blood Components (Hemolysis)
- Pressure Drop
- Mechanical Integrity
- Static Priming Volume
- Heat Exchanger Performance
- Defoaming
- Filtration Efficiency
- Flow Rate

**Substantial Equivalence Comparison:**
The CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating is substantially equivalent to the uncoated CAPIOX® SX10 as follows:

- Intended Use: Both devices are used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

  The integral heat exchangers are used to warm or cool blood and/or perfusion fluid as it flows through the device.

  The (detachable) hardshell reservoirs are used to store blood during extracorporeal circulation from both the venous line and the cardiotomy line (via gravity or vacuum assisted venous drainage procedures). The reservoirs contain a venous section that is comprised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoirs contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal.

  Both devices can be used in procedures lasting up to 6 hours.

- Principles of Operation and Technology: Both devices operate in a manner where blood is collected into the reservoir via gravity or external vacuum. Blood may enter via the venous inlet port and/or the cardiotomy inlet port. The reservoir contains filtering devices to remove particulate matter and air. Blood is then pumped from the reservoir into the heat exchanger device whereby blood temperature is controlled.

After the blood exits the heat exchanger, it enters the oxygenator device whereby gas transfer (introduction of oxygen and removal of carbon dioxide) occurs. After gas transfer has occurred, the blood exits the device and is pumped towards the patient.

- Design and Materials: The design and the materials of the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating and the uncoated predicate device are exactly the same with the exception of the X-Coating polymer that is applied to the coated device.

- Performance: Comparisons of the performance of the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating and the uncoated predicate device were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the coated and uncoated devices.

**Substantial Equivalence Summary:**
In summary, the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating and the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

**Additional Safety Information:**
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of $10^{-6}$.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo conducted biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- Terumo conducted studies for materials characterization, including physico-chemical profiles of aged and nonaged devices.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

- Safety evaluations of the polymer coating were conducted by Terumo Corporation (Japan). Those studies include:

  - Acute Systemic Toxicity Testing (in Rats)
  - Genotoxicity Testing – Bacterial Reverse Mutation
  - Genotoxicity Testing – Chromosome Aberration
  - Sensitization (in Guinea Pigs)

**Conclusion:**
In summary, the CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the uncoated SX10 device that was cleared on October 16, 1996 (K960074).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2001

Mr. Gary A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K010443
Trade Name: CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator.
Regulatory Class: II
Product Code: DTZ
Dated: September 28, 2001
Received: October 1, 2001

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):**

**Device Name:** **CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating**

**Indications For Use:**

The CAPIOX® SX10 Hollow Fiber Oxygenator with/without Hardshell Reservoir with X-Coating is used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

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Garry A. Courtney 2/12/01

Garry A. Courtney
Regulatory Affairs
Terumo Medical Corporation

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010443

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)